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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,514

06/09/2005

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Q88061

1878

23373 7590 01/22/2009
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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Applicants' arguments, filed 12/1/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1, 8, 9, 11, 12 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kitazawa et al., (previous) in view of Ishihara et al., (previous) and in further view of Salpekar et al., and Shah.

Applicant argues that the instant composition is obvious over Salpekar and Shah. A 132 declaration from Tsuyoshi Naganuma was filed attesting to a comparative test allegedly based on the teachings of Shah. Applicant's data supports the limitation of claim 1 where 85% dissolution time is not more than 60 minutes in a dissolution test. However, these results are not unexpected since Salpekar teach the use of pregelatinized starch for imparting a short dissolution time, i.e. about 20 minutes or less for 80% or more of active the active compound to dissolve. The artisan would reasonably expect the claimed dissolution rate based on the teachings of Salpekar.

In the comparative example is also improper. The data shows a much higher dissolution rate for Examples 1 and 2 compared with the other compositions, but applicant used 22 and 45 times more KMD-3213 in the other compositions. So, of

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course, the dissolution rates are going to be much lower. Applicant states that the reason for this vast increase in KMD-3213 for the other composition is because Shah uses a high dosage of acetaminophen. However, the high dosage of acetaminophen was for purposes of treatment not dissolution rate. The artisan would have understood that drugs vary in dosage, and would, therefore, formulate a tablet with the proper dosage of drug incorporated therein. Nevertheless, the rejection is over Kitazawa et al., Ishihara et al. as well, and how it would have been obvious to use partially pregelatinized starch in the composition of Kitazawa, which teaches a solid dosage form of KMD-3213. Applicant's arguments are unpersuasive.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

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Supervisory Patent Examiner, Art Unit 1612